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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,259	02/07/2001	Cristobal Guillermo dos Remedios	13388	4496

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EXAMINER

CHEU, CHANGHWA J

ART UNIT PAPER NUMBER

1641

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/778,259

Applicant(s)

REMEDIOS ET AL.

Examiner

Jacob Cheu

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/28//2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11,12 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 13-26 and 28-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Applicant's amendment filed on August 28, 2003 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 2, 10 are cancelled.
2. Claims 1, 3, 4, 12 are amended to the instant application.
3. Currently, claims 1, 3-9, 11-12, 27 are under examination. Claims 13-26, 28-33 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended claim 4 recites a binding partner including a protein, a nucleic acid molecule, or a combination thereof. There is no support of the "combination" of the nucleic acid and a protein being a binding partner from the specification. At page 8, line 25, applicant describes a hybrid of RNA and DNA. Further down, line 28, applicant describes the binding partnership may also comprise nucleic acid molecule and nucleic binding proteins. No where the instant specification describes a binding partner being a combination of a protein and nucleic acid molecule as recited in claim 4. Accordingly, in light of specification, applicant did not possess the recited invention as the time the invention was made.

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4. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claim recites that the binding partner could be in the combination of a protein and nucleic acid molecule. However, the specification discloses a method of detecting a toxicant in the sample by measuring the dissociation or inhibition of binding between the binding partners. It is well-known that the binding partnership includes protein-protein, protein-DNA, DNA-DNA or DNA-RNA. Nevertheless, applicant recites a binding partner in a combination of protein-DNA. It would impose undue experimentation to one skill in the art to determine the dissociation of the binding constant in the system. For instance, what constant applicant is measured with respect to such combination, i.e. protein-protein, DNA-DNA, or protein-DNA or DNA-protein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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5. Claims 1, 3, 4, 5, 6, 7 and 11 are rejected under 35 U.S.C. 102 (e) as anticipated by Wu et al.. (USP 6207391)

Wu et al. teach an assay for screening compounds of modulating protein-receptor binding based on increase or decrease of the binding in comparison with the binding absence of the modulators. (claim 1) Wu et al. teach the binding partners including proteins, receptors, enzymes, and substrates of enzymes. (claim 1, Col. 4, line 5-15) The proteins, receptors or enzymes taught by Wu et al. all contain sulfhydryl group. Wu et al. also teach immobilizing binding partner to a solid support, i.e. polystyrene. (Col. 15, line 53-55)

Response to Applicant's Arguments

6. Claims 1-10, 12 and 27 rejection under 35 U.S.C. 102(a) as anticipated by Kekic et al. (Electrophoresis (1999) 20: 2053-2058) is withdrawn.

7. Applicant argues that the Wu et al. reference does not teach a method for the identification of a “toxicant”. (emphasis added; See page 6, third paragraph) Furthermore, applicant points out that the Wu et al. reference is for identifying therapeutics rather than environmental toxicant. Examiner disagrees with this notion because applicant clearly defines the toxicants by stating that “toxicants may or may not necessarily be “toxic” in the sense that they are capable of inducing death or a living organism or inducing one or more mutations in the genome..... *Toxicants may also vary their toxicity depending on concentration or time of exposure.*” (See page 7, line 21-24) Therapeutics, many times indeed could become “toxic”, e.g. inhibit cellular protein binding, at a higher concentration or prolonged time of exposure. Therefore, Wu et al. teachings encompass the instant inventions.

Allowable Subject Matter

8. Claims 8, 9, 12, 27 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. The following is an examiner's statement of reasons for allowance: no prior art suggests or teaches measuring dissociation of actin/ actin-binding protein or DnaseI or cofilin in binding assay for in detecting the presence of a toxicant. The closest prior art is Kekic et al. (Electrophoresis (1999) 20: 2053-2058) where Kekic et al. teach determining protein-protein interaction to evaluate the presence of certain environmental metals, herbicides. However, Kekic et al. use polyacrylamide gel electrophoresis (PAGE), whereas the instant invention recites an easier and inexpensive assay by immobilizing actin, DNase I or cofilin on a solid substrates.

Conclusion

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu

Examiner

Art Unit 1641



October 28, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

10/21/03